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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/944,807	08/31/2001	Birgit Jung	1/1144	1468

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EXAMINER

KEMMERER, ELIZABETH

ART UNIT	PAPER NUMBER
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1646

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DATE MAILED: 09/15/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/944,807

Applicant(s)

JUNG ET AL.

Examiner

Elizabeth C. Kemmerer, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 06 August 2003.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11-69 and 72 is/are pending in the application.
- 4a) Of the above claim(s) 11-64 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 65-69 is/are rejected.
- 7) ☒ Claim(s) 72 is/are objected to.
- 8) ☒ Claim(s) 11-69 and 72 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other:

DETAILED ACTION

Status of Application, Amendments, And/Or Claims

The amendment filed 06 August 2003 (Paper No. 10) has been entered in full. Claims 1-10, 70, 71 and 73 are canceled. Claims 11-64 remain withdrawn from consideration as being directed to a non-elected invention. Claims 65-69 and 72 are under examination.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Withdrawn Objections And/Or Rejections

The objection to the claims as set forth at p. 3 of the previous Office Action (Paper No. 8, 06 February 2003) is *withdrawn* in view of the amended and canceled claims (Paper No. 10, 06 August 2003).

The rejection of claims 6 and 70 under 35 U.S.C. § 112, first paragraph, as set forth at pp. 3-4 of the previous Office Action (Paper No. 8, 06 February 2003) is *withdrawn* in view of the canceled claims (Paper No. 10, 06 August 2003).

The rejection of claims 1-4, 7-10, 65-68 and 71-73 under 35 U.S.C. § 102(b) as being anticipated by Takano et al. as set forth at pp. 6-7 of the previous Office Action (Paper No. 8, 06 February 2003) is *withdrawn* in view of the canceled claims and the evidence submitted by Applicant with the response (Paper No. 10, 06 August 2003). Specifically, Christophe et al. (2002, Scand. J. Immunol. 56:470-476) disclose that the "substance", LXA₄, used in the method by Takano et al., does not act through the

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FPRL1 receptor, and thus cannot be interpreted as a substance having the properties as recited in the claims.

The rejection of claims 5 and 69 under 35 U.S.C. § 103 as set forth at pp. 7-8 of the previous Office Action (Paper No. 8, 06 February 2003) is *withdrawn* in view of the canceled claims and evidence (Christophe et al.) submitted with the response (Paper No. 10, 06 August 2003) as discussed above.

35 U.S.C. § 112, First Paragraph

Claims 65-69 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the recited methods wherein the FPRL-1 receptor comprises SEQ ID NO: 2, does not reasonably provide enablement for the methods reciting variants of SEQ ID NO: 2. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims. The basis of this rejection is set forth at pp. 4-6 of the previous Office Action (Paper no. 8, 06 February 2003).

Applicant's arguments (pp. 5-6, Paper No. 10, 06 August 2003) have been fully considered but are not found to be persuasive for the following reasons.

Applicant argues that the specification provides sufficient guidance to enable one skilled in the art to generate variants, mutants and fragments within the scope of the claims using routine methods. Applicant argues that the variants, mutants and fragments can be routinely tested for functional equivalency using binding assays. Applicant states that, while preparation and screening of a large number of samples

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may be required, the teaching of the specification and the level of skill in the art renders such experimentation routine. This is not found to be persuasive. It is important to note that the instant claims do not recite any structural limitations for the recited variants, mutants or fragments of SEQ ID NO: 2. Therefore, an infinite number of structures would have to be screened. Furthermore, the specification provides only one structure having the required activity, i.e., SEQ ID NO: 2. The instant fact pattern closely resembles that in Ex parte Maizel, 27 USPQ2d 1662 (BPAI 1992). In Ex parte Maizel, the claimed invention was directed to compounds which were defined in terms of function rather than sequence (i.e., "biologically functional equivalents"). The only disclosed compound in both the instant case and in Ex parte Maizel was the full length, naturally occurring protein. The Board found that there was no reasonable correlation between the scope of exclusive right desired by Appellant and the scope of enablement set forth in the patent application. Even though Appellant in Ex parte Maizel urged that the biologically functional equivalents would consist of proteins having amino acid substitutions wherein the substituted amino acids have similar hydrophobicity and charge characteristics such that the substitutions are "conservative" and do not modify the basic functional equivalents of the protein, the Board found that the specification did not support such a definition, and that the claims encompassed an unduly broad number of compounds. Such is the instant situation. Clearly, a single disclosed sequence does not support claims to any variant, mutant or fragment having the same activity.

The instant fact pattern is also similar to that in *In re Hyatt*, 708 F.2d 712, 218 USPQ 195 (Fed. Cir. 1983), wherein a single means claim which covered every conceivable means for achieving the stated purpose was held nonenabling for the scope of the claim because the specification at most disclosed only those means known to the inventors. When claims depend on a recited property, a fact situation comparable to *Hyatt* is possible, where the claim covers every conceivable structure (means) for achieving the stated property (result) while the specification discloses at most only those known to the inventor. See also *Fiers v. Sugano*, 984 F.2d 164, 25 USPQ2d 1601 (Fed. Cir. 1993), and MPEP § 2164.08(a). The specification discloses a single sequence. It is clear that some aspect of the sequence is required for the FPRL-1 receptor activity. However, the specification fails to disclose which regions of SE QID NO: 2 are critical for activity, and the claims fail to recite any sequence limitations. Thus the skilled artisan would have to resort to trial and error experimentation to identify compounds meeting the functional limitations of the claims, even though a suitable assay for binding activity is disclosed. Finally, as was found in Ex parte Hitzeman, 9 USPQ2d 1821 (BPAI 1987), a single embodiment may provide broad enablement in cases involving predictable factors such as mechanical or electrical elements, but more will be required in cases that involve unpredictable factors such as most chemical reactions and physiological activity. See also In re Fisher, 427 F.2d 833, 839, 166 USPQ 18, 24 (CCPA 1970); Amgen Inc. v. Chugai Pharmaceutical Co. Ltd., 927 F.2d 1200, 1212, 18 USPQ2d 1016, 1026 (Fed. Cir.), cert. denied, 502 U.S. 856 (1991).

Due to the large quantity of experimentation necessary to determine what structural features are required for the binding activity, the lack of direction/guidance presented in the specification regarding active variants, mutants or fragments of SEQ ID NO: 2, the absence of working examples directed to same, the complex nature of the invention, the state of the prior art which establishes the unpredictability of the effects of mutation on protein structure and function, and the breadth of the claims which fail to recite any structural limitations, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim Objections

Claim 72 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Conclusion

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

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A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

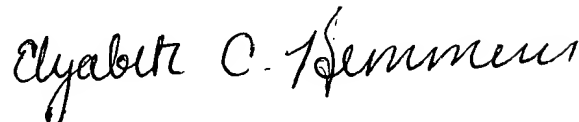
This application contains claims 11-64 drawn to an invention nonelected with traverse in Paper No. 7 (18 November 2002). A complete reply to the final rejection must include cancelation of nonelected claims or other appropriate action (37 CFR 1.144) See MPEP § 821.01.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Elizabeth C. Kemmerer, Ph.D., whose telephone number is (703) 308-2673. The examiner can normally be reached on Mondays through Thursdays from 6:30 a.m. to 4:00 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler, Ph.D., can be reached on (703) 308-6564.

Official papers filed by fax should be directed to (703) 308-9306. Faxed draft or informal communications with the examiner should be directed to (703) 308-0294.

ECK



ELIZABETH KEMMERER
PRIMARY EXAMINER